URGENT

Minister Nash_DLO <Minister.Nash.DLO@Health.gov.au>
Sent by: "ROCKS, Martin" <Martin.Rocks@health.

11/05/2015 15:53
1 attachment

To MinCorro <MinCorro@health.gov.au>,
cc
bcc
Subject FW: TGA LVT Abolition - RIS Review Request [SEC=UNCLASSIFIED]

MC15-007924

11.11.14k - Assist. Min. Health - LVT Regulatory Impact Statement.pdf

Due MPEE 12:00PM 18/5/15
Due MO 18/5/15 4:30PM

UNCLASSIFIED

M response please due 18 May 2015 – pls include a page of talking points (note the meeting is not scheduled for 12 May)

Thanks

Martin

RECEIVED
11 MAY 2015
Division: TGA
Minister: FN
Milestone: 10 | 15 | 20
INFO
VIP
PM

From: WOOD, Emma
Sent: Friday, 8 May 2015 5:52 PM
To: Minister Nash_DLO
Subject: FW: TGA LVT Abolition - RIS Review Request [SEC=UNCLASSIFIED]
Importance: High

Hello Martin,

As discussed. Would you kindly ask the TGA to prepare a response, with TPs for a meeting – I will let you know when I have secured a date (it won't be 12 May as Troy suggests).

Many thanks,
Emma

Emma Wood
Adviser
Office of the Assistant Minister for Health
Ph: (02) 6277 7440
Mob: 0412 621073
emma.wood@health.gov.au

From: Troy Williams - ADIA [mailto:troy.williams@adia.org.au]
Sent: Friday, 8 May 2015 3:33 PM
To: WOOD, Emma
Cc: Elise Mizzi - ADIA
Subject: TGA LVT Abolition - RIS Review Request [SEC=No Protective Marking]
Importance: High

Dear Emma

Please find attached correspondence to the Assistant Minister (original in the mail) concerning proposal to revise arrangements associated with fees and charges levied by the Therapeutic Goods Administration (TGA).

The issue at hand is an assessment carried out by the TGA indicates that the proposed abolition of the Low Value Turnover (LVT) scheme and its replacement disadvantages small business. Curiously, this finding was omitted from the Regulatory Impact Statement (RIS)

As you available late on the afternoon on Tuesday, 12 May 2015, or the early part of the following day to meet briefly to discuss this?

Thanks and regards

Troy

Troy R Williams FAIM MAICD
Chief Executive Officer ■ Australian Dental Industry Association

ADIA

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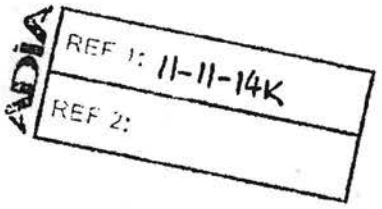
UNCLASSIFIED

Australian Dental Industry Association | ADIA



Ref: 11.11.14K — 8 May 2015

Sen. Hon. Fiona Nash
Assistant Minister for Health
PO Box 6100 – The Senate
Parliament House
CANBERRA ACT 2600

Dear Minister

RE: TGA Low Value Turnover Fee Exemption Abolition – Urgent review required

As the peak business organisation representing manufacturers and suppliers of dental products, the Australian Dental Industry Association (ADIA) requests an urgent review of proposals to amend fees and charges levied by the Therapeutic Goods Administration (TGA). The rationale for this request is that an assessment made by the TGA indicates that the reforms will result in higher fees and charges for small business.

Therapeutic goods entered in the Australian Register of Therapeutic Goods (ARTG) can be lawfully supplied in Australia and there is a fee to business associated with placing products on the ARTG. Presently, the TGA permits a business to claim an exemption from this fee if the turnover for the product/s under the ARTG entry is equal to or less than fifteen times the annual charge for that entry, an arrangement known as the Low Value Turnover (LVT) exemption. The TGA's proposal is to abolish the LVT exemption and only allow a business to claim an exemption if there is no turnover.

From the outset, ADIA has had concerns that the proposal to abolish the LVT exemption will disadvantage small business. For this reason, ADIA requested that the TGA review the impacts of the proposal on businesses in the dental industry and this request was assented to. ADIA received the outcome of the TGA's assessment (dated 16 February 2015) which found that the proposals will increase TGA fees and charges for small businesses by 30.2%. Although the TGA's assessment was based upon a small sample of businesses, there is no reason a further review of a larger sample would yield different results.

The accuracy of the Regulatory Impact Statement (RIS) prepared by the TGA must be questioned as it makes no reference to the TGA's review that clearly establishes that small businesses will face a significant increase in fees associated with placing products on the ARTG.

Beyond threatening the commercial viability of small businesses and therefore the ability of these businesses to create jobs, the proposal will have adverse impacts on patient interests due to the withdrawal of products from the market. Certainly, the ADIA member businesses'

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assessment reflects the TGA's own conclusions, as set out in the RIS, that around fifty percent of currently exempted entries which will no longer qualify for an exemption will be taken off the ARTG. The genuine concern is that this will result in some specialist products being withdrawn from the Australian marketplace.

Given that the RIS has not addressed the adverse cost impacts on small business, ADIA believes that a more comprehensive review of the proposal is merited. If, as there is reason to believe, the proposal will adversely affect small business it should be withdrawn with a view to drafting a more equitable solution.

We look forward to discussing this matter with you.

Yours faithfully

Troy R Williams FAIM MAICD
Chief Executive Officer

Australian Government
Department of Health
Therapeutic Goods Administration

Mr Troy Williams
Chief Executive Officer
Australian Dental Industry Association
GPO Box 960
Sydney NSW 2001

Our Reference: EAC 426777

Dear Troy

Low value turnover scheme

Thanks for your letter of 8 January and follow-up email on 12 February. We are glad that ADIA is a strong advocate of reforms to deliver a regulatory framework for dental products that is based on a risk management approach designed to ensure public health and safety, while at the same time freeing industry from any unnecessary regulatory burden. In this context, ADIA is supportive of reform to the LVT scheme that will reduce the administrative workload of businesses in the dental industry.

My colleagues have now "run the numbers" with the five sponsors you listed, to assess the impact of the proposed changes to the low value turnover scheme. TGA is proposing a reduction of 5% in annual charges for medical devices class of II and above but annual charges for all types of class 1 medical devices will remain unchanged.

Our analysis of the maximum impacts is shown in the table overleaf. However it is important to note:

- **A number of products may be eligible for criteria as an "essential good"** for public health and thus be eligible for waiver of fees. We haven't tried to determine which dental products would qualify as we will be assessing waiver applications on a case by case basis. But I would imagine that a product such as a highly specialised forceps could potentially be eligible.
- Our discussions with other parts of the devices and medicines industry is that they will potentially use the changes to the scheme to identify products that are selling in small quantities, don't particularly fill any specialist niche, and are possibly costing more for the sponsor to support in the market than the profits obtained. **These products would them be withdrawn from the ARTG and also not pay annual charges.** Of course this action would be a commercial decision of the sponsor.
- **New class 1 devices (other than class 1 measuring and class 1 sterile), entered on the Register after the commencement of the proposed scheme would**

benefit more than at present, as our data shows that most devices under this category are not currently seeking exemptions under the current LVT scheme as the annual charge of $80 for a class 1 device is less than the $155 LVT application fees. Given that there would not be any requirement to make an application (or pay application fees) for exemption under the new scheme the new class 1 devices would not incur annual charges until they commence generating turnover.

- Existing class 1 devices will not be exempt as they would not meet the primary criterion for transitional entries (at 1 July 2015) that they would have been exempted under the LVT scheme on the basis of $0 turnover in the last two years before the commencement of the new scheme (i.e. 2013-14 and 2014-15). If a sponsor is going to be impacted significantly because of this, **they have the option to cancel the old entry and include a brand new entry without cost which would be eligible for exemption under the new scheme until that entry commences turnover.** The new device entry would have a new ARTG number but as there is no labelling requirement for such devices so this should not have any impact on them.

Company Name	Current Charges	Proposed Charges	Impact
1. [redacted]	$8,445	$23,370	($14,925)
2. [redacted]	$74,830	$85,810	($10,980)
3. [redacted]	$4,085	$6,140	($2,055)
4. [redacted]	$26,610	$33,690	($7,080)
5. [redacted]	$5,980	$7,260	($1,280)
Total	**$119,950**	**$156,270**	**($36,320)**

Note: for comparison purposes, we assumed the charges [redacted] would have paid in 2014-15 had they made the LVT application in time and compared that with the charges that would become payable under the proposed model.

The fact that one of the above ADIA members, [redacted] failed to make the LVT application in 2014-15 and paid the full charges is indicative that the administrative burden of applying for the exemption under this scheme can outweigh the benefits at present. We hear of varying figures, but TGA has often been told that the cost of contracting an independent accountant and the costs of creation and verification of LVT lists are more than $ 10,000 per sponsor. So taking the potential cost saving of reducing this paperwork plus the other factors listed in the points on the previous page my expectation is that overall at worst it would be cost neutral for these representative member companies.

The sole aim of the proposed changes to the low value turnover scheme is to reduce red tape for business, particularly small business who are currently compelled to submit declarations audited by an independent accountant, and have such declarations submitted by a particular date.

These two requirements are extremely unpopular with many, if not most sponsors and result from inflexibilities in our Act. Unless if we change the Therapeutic Goods Act at this stage, we cannot merely "tweak" the current LVT scheme to remove these requirements. Furthermore, with the government's legislative programme and the nature of the changes that would be required in modifying the Act in this way, changes to the LVT scheme could not be implemented until July 2016 at the earliest, and possibly later. This delay would be unacceptable to many in industry. The proposed introduction of a "no value turnover" scheme means that we can make the changes through regulation and we plan to have them in force by July 1 this year.

If you would like to meet to discuss this analysis and other issues relating to LVT we would be happy to do so.

Yours sincerely

John Skerritt
National Manager
16 February 2015

Australian Government

Department of Health
Therapeutic Goods Administration

Mr Troy Williams
Chief Executive Officer
Australian Dental Industry Association
GPO Box 960
Sydney NSW 2001

Our Reference: R15/259683

Dear Mr Williams,

Review of the low value turnover (LVT) annual charge exemption scheme

Thank-you for your ongoing feedback and participation in the review of the LVT scheme. Your input has been extremely valuable in the design of a replacement scheme that will improve equity between sponsors, simplify participation requirements, and reduce red tape for business and the TGA, as well as result in a reduction in the rates of annual charges for some categories of products.

A Regulation Impact Statement (RIS) has now been prepared and endorsed by the Assistant Minister for Health. The RIS documents the proposal we have consulted with you on, to introduce a new annual charge exemption (ACE) scheme to replace the LVT scheme. The RIS is available on the TGA website.

Again, thank-you for your ongoing involvement and I can be contacted on phone 02 6221 6910 with any questions on the progress of the new scheme or the RIS.

Yours sincerely

Nicole McLay
Assistant Secretary, Regulatory Business Services Branch

5 May 2015

ADIA 7 MAY 2015 REF : 11-11-14K

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TGA Health Safety Regulation

Australian Government
Department of Health
Therapeutic Goods Administration

Regulation impact statement

Low value turnover exemption scheme

Version 1.1, March 2015

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <http://www.tga.gov.au>.

Version history

Version	Description of change	Author	Effective date
V1.1	Original publication	Regulatory Decision Review Section, Regulatory Business Services Branch	26/03/2015

Contents

Introduction

The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating therapeutic goods including medicines, medical devices, biologicals, blood and blood products.

This Regulation Impact Statement (RIS) has been prepared by the TGA. The purpose of this RIS is to assist Australian Government decision making on how to address the problems that have been identified in relation to the Low Value Turnover Exemption Scheme (the LVT scheme)[1] and determine the best option to address the problems. It also summarises the consultation process that has been undertaken with stakeholders to explore options that may address the problems that have been identified with the current policy.

The TGA released the 'Review of the Low Value Turnover Exemption Scheme' consultation paper in April 2014.

The RIS concludes with a recommended proposal, outlining the proposed amendments to the requirements for Government consideration.

Background

Cost recovery at the TGA

A therapeutic good must be listed, registered or included in the Australian Register of Therapeutic Goods (the Register) before it can be supplied in Australia.

The TGA undertakes a number of pre market functions, including evaluation of high risk therapeutic goods, before a therapeutic good is entered on the Register and monitors products once they are on the market (post market). The TGA also assesses the suitability of medicines and medical devices for export from Australia. In addition, the TGA regulates manufacturers of therapeutic goods to ensure they meet acceptable standards of manufacturing quality.

The full cost of these regulatory services is recovered from industry. The legal authority for the fees and charges is prescribed in the *Therapeutic Goods Act 1989* (the Act), the *Therapeutic Goods (Charges) Act 1989* (the Charges Act) and subordinate regulations.

The cost recovery arrangements broadly cover regulatory activities in relation to:

- Prescription medicines
- Non-prescription medicines / over the counter (OTC) medicines
- Complementary medicines
- Medical devices, including in-vitro diagnostic (IVD) devices
- Compliance with Good Manufacturing Practice (GMP) Blood and blood products
- Biologicals.

Fees are charged for applications for entry on the Register and for assessment of the data in support of the application. The revenue from these fees primarily funds the costs of pre-market

[1] The low value turnover exemption scheme (the LVT scheme) allows sponsors to seek an exemption from payment of annual charges for entries where the annual turnover is less than or equal to 15 times the annual charge for that Register entry.

assessment services. The fees, prescribed in the Therapeutic Goods Regulations 1990 (the Regulations), are reviewed annually to ensure they reflect the underlying costs of providing these services in accordance with the Australian Government Cost Recovery Guidelines.

Annual charges to maintain an entry on the Register are levied to recover costs that cannot be reasonably assigned to individual sponsors, or where such assignment would act as a deterrent to the effective delivery of the TGA's post market function. These charges fund post-market regulatory activities such as the monitoring of product safety and of sponsor compliance with regulatory obligations. The Therapeutic Goods (Charges) Regulations 1990 (the Charges Regulations) prescribe varied levels of charges for different classes of therapeutic goods, based on the level of risk of the type of good.

Post market compliance and monitoring functions include the following activities:

- Management and processing of adverse drug reaction reports
- Management and processing of recalls of therapeutic goods, including recalls for product correction
- Testing of therapeutic goods by the TGA laboratories
- Post-market compliance reviews for listed complementary medicines and class 1 (low risk) medical devices
- Management of advertising and complaints resolution functions
- Other regulatory costs which cannot be easily assigned to individual sponsors or products.

Annual charges

All therapeutic goods are required to be entered on the Register before they are supplied in or exported from Australia, unless exempted by the Act.

Sponsors are required to pay an annual charge to maintain their entries on the Register, other than for entries which are specifically exempted (such as export only entries).

Table 1 illustrates the current rate of annual charge for each type of therapeutic good, prescribed by the Charges Regulations and based on the level of risk for the type of good.

Table 1:2014-15 Annual charges

Type of therapeutic good	Annual charge $
Prescription Medicines – Biological	6,585
Prescription Medicines – Non-Biological	3,955
Registered Non Prescription (OTC) Medicines	1,350
Listed (Complementary) Medicines	965
Medical Device Class I	80
Medical Device Class I Measuring and Sterile	615

Type of therapeutic good	Annual charge $
Medical Device Class IIa and IIb	940
Medical Device Class III and AIMD	1,210
Biologicals Class 1	615
Biologicals Class 2, 3 and 4	6,125
Other Listed Therapeutic Goods (e.g. tampons and disinfectants)	770
Other Registered Therapeutic Goods (e.g. tampons and disinfectants)	1,480

Notes:
1. A good entered on the Register at any time during a financial year incurs a full year's annual charge, unless an exemption is granted on the basis of low value turnover.
2. There is currently no annual charge for export only goods.
3. The annual charge for in vitro diagnostic (IVD) medical devices that were not included in the Register prior to the commencement of the new regulatory framework on 1 July 2010 and therefore has been set at zero for the period to 30 June 2015, which covers transition to new regulatory arrangements.

Low value turnover exemption

History and objectives of the LVT scheme

The LVT scheme (previously known as the low value low volume scheme) has been operating since 1990.

While records are limited on the intent of the scheme upon introduction, it is understood that the scheme was initially intended to assist herb growers and small companies making medical appliances[2] whose turnover on a number of product lines might only be a few hundred or a few thousand dollars.[3]

The scheme was established by provisions in the Regulations[4] which allow sponsors to apply for an exemption from the annual charge for a Register entry if the turnover of that entry in a financial year is of low value. At the time of implementation, the regulations avoided linking annual charge exemptions to a company's gross turnover. Consequently, charges were linked to individual Register entries without any limitation as to the number of entries or the company's size.

However, the therapeutic goods industry has changed significantly since the 1990s. For example, in the early 1990's the complementary medicines industry in Australia was small, with the regulatory framework covering not only producers of finished products, but also herb growers.

[2] Now referred as medical devices in the therapeutic goods legislation.
[3] Parliament of Australia – Senate Hansards <http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;db=CHAMBER;id=chamber%2Fhansards%2F1990-12-20%2F0216;query=Id%3A%22chamber%2Fhansards%2F1990-12-20%2F0000%22>
[4] The regulations for the current LVT scheme (*not the original provisions*) are set out in annexure A

The current domestic market for complementary medicines is estimated to be worth nearly $2 billion[5].

The current LVT scheme allows sponsors to seek an exemption from payment of annual charges for entries where the annual turnover is less than or equal to 15 times the annual charge for that Register entry.

In order to ensure full cost recovery of post market regulation, annual charges are set by allowing for the value of exemptions predicted to be granted (expected to be over 50% of total annual charges in 2014-15). As a result, some businesses are paying more for their charges to compensate for those businesses who will receive LVT exemptions. This is regarded as a form of cross subsidisation. Additionally, LVT exemptions increase each year, increasing pressure to increase the rates of annual charges.

Applying for an exemption

The process for applying for an LVT exemption is set out in the Regulations. A sponsor must submit a completed application within a prescribed timeframe, together with a prescribed application fee. The fee is currently $155 per Register entry, capped to a maximum application fee of $15,500 per financial year per sponsor. Therefore, a sponsor who applies for more than 100 LVT exemptions does not pay more than $15,500. However each product must be individually assessed for low value turnover.

A completed LVT application comprises:

- **For new Register entries (entries coming on the Register at any time of the financial year on or after 1 July)**: an LVT application detailing an **estimate of turnover** of the entry in the current financial year.
  - This estimate is verified at the beginning of the following year, through provision of a statement of actual turnover, signed by a third party accountant (an approved person). If this information is not provided within the prescribed timeframe (by 1 September), or the turnover for the year was above the relevant threshold, the full annual charge for the prior year becomes payable
  - The Secretary or their delegate may grant an extension of up to 28 days for providing the statement of actual turnover for the prior year.
- **For existing Register entries (entries on the Register at 1 July)**: an LVT application containing a **statement of actual turnover** of the entry in the previous financial year.
  - The statement is required to be signed by a third party accountant (an approved person) to certify the reported turnover and is to be received by the TGA before 2 September
  - No extension to this timeframe is available.
- Applications are required to be made by the specified deadline for each financial year. If the deadline is missed for any reason, the sponsor must pay the full annual charge for entries on the Register irrespective of whether the goods have been included in the Register for the full or part financial year. Subsequent cancellation of the entry from the Register does not void the debt. Where the deadline has been missed, the unplanned financial impact has affected some sponsors.

[5] Complementary Health Council Annual Report 2012 <http://www.chc.org.au/Resources/Documents/Annual%20Report/CHC%20Annual%20Report%20Final%20Published.pdf>

Current operation of the exemption

In 2013-14, 3,679 sponsors were invoiced for annual charges relating to 77,591 Register entries - totalling $100.478 million.

Of these, 1,001 sponsors applied for, and received, LVT exemptions (relating to 21,830 Register entries), totalling $49.931 million.

The exemptions resulted in net annual charge revenue of $50.547 million – only 50.3% of the invoiced annual charges in that year.

In addition, in 2013-14, sponsors paid a total of $2.086 million in LVT application fees.

Table 2 below provides a summary of the actual 2013-14 gross annual charges, LVT exemptions and net annual charge revenue, based on the rates of annual charges that were applicable for the 2013-14 financial year.

Table 2: 2013-14 Actual annual charges revenue and LVT exemptions

	Annual Charges	LVT Exemptions	Net Annual Charges	Annual Charges Revenue	LVT Exemptions	Net Annual Charge Revenue
Type of Therapeutic Good	**Number of Units**			**$**		
Prescription Medicines – Biological	1,038	577	461	6,674,340	3,710,110	2,964,230
Prescription Medicine – Non-Biological	13,652	9,027	4,625	52,696,720	34,844,220	17,852,500
Non Prescription (OTC) Medicines	3,769	1,399	2,370	4,816,620	1,793,100	3,023,520
Listed (Complementary) Medicines	13,119	4,500	8,619	12,407,480	4,247,860	8,159,620
Medical Device Class I (other than Class 1 Measuring and Class 1 Sterile)[6]	22,126	702	21,424	1,770,080	56,160	1,713,920
Medical Devices – Other than Class I	23,240	5,528	17,712	21,540,520	5,191,320	16,349,200
Other Therapeutic Goods (OTG)	647	97	550	571,880	88,230	483,650
Total	77,591	21,830	55,761	100,477,640	49,931,000	50,546,640

[6] The annual charge for a Medical Device Class 1 (other than Class1 Measuring and Class 1 Sterile) is much less than the LVT application fee.

What is the problem?

While a number of amendments have been made to the LVT eligibility threshold and application requirements since the introduction of the scheme, the general nature of the scheme and its primary criteria for eligibility (i.e. annual turnover) has remained the same.

Over the years, a number of challenges have arisen with the operation of the scheme which are discussed below.

The scheme is no longer consistent with stated objectives

The original objectives of the LVT scheme were to provide exemptions to the therapeutics industry which manufacture small volume products and address the concerns of herb growers and small companies making medical appliances whose turnover on a number of product lines might only be a few hundred or a few thousand dollars.

However, in the absence of any specific criteria in the Regulations about the size of the sponsor responsible for the Register entry for which the exemption is claimed, the benefit extends to companies of all sizes, and not only to those small companies whose turnover on a number of product lines is low.

Contrary to the intended objectives of the scheme, the main beneficiaries of the contemporary LVT scheme are not small business. In any event, most schemes introduced by government to assist small business help them enter the market, rather than stay in the market. Table 3 below illustrates a summary of the gross annual charges, LVT exemptions and net annual charges for the 20 highest invoiced sponsors (annual charges invoiced before any exemption is applied) in 2013-14. As demonstrated by the figures below, these sponsors now account for more than 50% of all LVT exemption benefits. Furthermore, 11 of the 20 sponsors pay less than 50% of the gross annual charges they each incur.

In contrast, a large number of small business sponsors, who generally only hold a few entries on the Register, did not receive LVT exemptions. The contrast may result, among other reasons, from small businesses not having dedicated regulatory compliance officers/advisers. In one case reported to us, a small business did not apply because they didn't have an accountant. In other cases it is because their financial records do not produce financial information by Register entry and organising their records in this manner would be more burdensome than paying the full invoiced charge.

For sponsors of class I (lowest risk) medical devices (other than those in the sterile or measuring function categories) the annual charge is much less than the LVT application fee. Therefore, there is no incentive to apply for an LVT exemption.

The sole criterion to access the current LVT scheme is that the value of the turnover of the individual Register entry is below the threshold value. This criterion doesn't take into account total turnover of the sponsor or the company size.

Table 3: Top 20 Sponsors by gross annual charges revenue in 2013-14

	Gross Annual Charges		LVT Exemptions		Net Annual Charges	
	QTY	$	QTY	$	QTY	$
Top 20 Sponsors who receive LVT exemptions	11,112	40,701,750	7,839	28,814,515	3,273	11,887,235
Remaining 3,659 Sponsors	66,479	59,775,890	13,991	21,116,485	52,488	38,659,405
Total	77,591	100,477,640	21,830	49,931,000	55,761	50,546,640
Top 20 Sponsors	14%	41%	36%	58%	6%	24%
Remaining 3,659 Sponsors	86%	59%	64%	42%	94%	76%
Total	100%	100%	100%	100%	100%	100%

Compliance with cost recovery principles

In 2002, the government introduced a Cost Recovery Policy (the Policy) and issued the *Australian Government Cost Recovery Guidelines July 2014* (the Cost Recovery Guidelines)[7]. As a cost recovered operation, the TGA is required to establish and maintain a system of fees and charges that comply with the Cost Recovery Guidelines.

The Cost Recovery Guidelines aim to ensure that fees and charges applied for government services:

- Are legally applied
- Are cost effective to implement
- Are cost reflective of the services performed
- Do not impede competition or innovation
- Avoid cross subsidisation.

The LVT exemption provisions were introduced in 1990, much earlier than the Policy.

Under current annual charge settings, a significant number of Register entries which are subject to TGA's post market activities are not paying their share of the costs associated with the performance of these functions – these costs are paid disproportionately by sponsors of Register entries for which the exemption is not claimed. Therefore, the current take up of the LVT scheme leads to inconsistency with the Cost Recovery Guidelines.

[7] Australian Government Cost Recovery Guidelines, Resource Management Guide No. 304 <http://www.finance.gov.au/sites/default/files/australian-government-cost-recovery-guidelines.pdf>

Table 4 below details the portion of LVT benefit as a percentage of gross annual charge revenue.

In addition, the benefit provided by the scheme seems to differ between groups of therapeutic goods - the table below shows that the proportion of LVT benefit as a percentage of gross annual charge revenue varies significantly from one group of therapeutic products to another. For example, LVT benefits claimed are only 24% of expected total gross annual charges revenue in relation to medical device Register entries; while for chemical prescription medicines the value is much higher at 66%.

Table 4: 2013-14 Annual Charge Revenue and LVT Exemption by Type of Therapeutic Good

Type of Therapeutic Good	Annual Charge Revenue $	LVT Benefit Received $	Fees After LVT Benefit $	LVT as a % of Gross Revenue $
Prescription Medicines – Biological	6,674,340	3,710,110	2,964,230	56%
Prescription Medicines – Non-Biological	52,696,720	34,844,220	17,852,500	66%
Registered Non-Prescription (OTC) Medicines	4,816,620	1,793,100	3,023,520	37%
Listed (Complementary) Medicines	12,407,480	4,247,860	8,159,620	34%
Medical Device Class I	1,770,080	56,160	1,713,920	3%
Medical Device – Other than Class I	21,540,520	5,191,320	16,349,200	24%
Other Therapeutic Goods (OTG)	571,880	88,230	483,650	15%
Total	100,477,640	49,931,000	50,546,640	50%

Administrative complexity and sponsor understanding of the processes

On the recommendation of the Australian National Audit Office (ANAO), the scheme was amended in 2009 to require sponsors to obtain third party certification of the reported turnover of Register entries for which an LVT exemption was sought, to ensure the eligibility of claims for exemption.

To overcome administrative difficulties faced by both the TGA and sponsors in implementing the new requirements, further amendments were made to the scheme in December 2011 and June 2012. These amendments respectively provided sponsors with more time to submit their LVT applications for new entries, and an additional opportunity to meet their obligations in relation to the 2009-10 and 2010-11 LVT exemptions for new entries.

Despite the amendments, issues remain in relation to sponsor compliance with certification requirements.

Eight validation processes were conducted between 2008 and 2013 to examine sponsor records relating to sales revenue and the mapping of these to Register entries to determine LVT eligibility. The validation processes comprised desk top reviews of sponsor records, and, for

select sponsors, were complemented by on-site validation meetings where further cross verification of LVT related records was conducted. During these meetings, the TGA identified repeat examples where sponsors had experienced difficulties in recording and accurately reporting the actual turnover of individual Register entries. Sponsors do not necessarily capture turnover by Register entry, other than to meet the requirements of the LVT scheme, and small business was disproportionately affected by these difficulties, given the smaller resource base and reporting system support.

The process for new entries is more complex than for existing entries as it requires sponsors to initially submit their applications on the basis of **estimated turnover for the current financial year**; and then subsequently submit a statement of **actual turnover**, signed by a third party accountant, in the following financial year. The process to verify the actual turnover of new entries occurs at the same time that the sponsor must make their application for exemption for existing entries. These two separate processes for new and existing entries, both with similar information requirements (i.e. both require the sponsor to provide a statement of actual turnover for the previous financial year), have been confused as being part of a single process.

As a result the TGA received informal feedback that some sponsors do not seek an LVT exemption because they consider the burden of preparing and submitting an LVT exemption application to be more administratively difficult than the value of the exemption in cases.

Sponsors also expressed concern with the strict deadlines outlined in the legislation for LVT applications for existing or new entries. If the deadline for submission of the LVT application is missed, the full annual charge becomes payable (there is no provision for an extension of time to make the application).

The LVT scheme also attracts a range of other complaints from across the therapeutics goods industry. Key areas of concern include the inflexible timing for annual LVT applications, the level and determination of key financial parameters and the magnitude of difference in outcome between products that are marginally eligible, compared to those that are marginally ineligible.

Why is government action needed?

Government action is needed because, as indicated above, there is no extant statement of policy to guide the LVT scheme. The lack of a policy statement makes it difficult to objectively assess the scheme's effectiveness or its contemporary relevance. The LVT scheme was introduced in 1990 and, as such, predates both the National Medicines Policy established in 1999 and the introduction of full cost recovery for the TGA in 1998.

The current scheme does not meet the original intent of providing assistance to small business and is inconsistent with other Government policy, such as the Cost Recovery Policy.

In 2009, the ANAO recommended that tighter controls be applied to verifying product eligibility for the scheme. In response, the TGA introduced additional requirements related to independent certification of product turnover values. While this has improved governance of the scheme, the certification process triggers complaints from industry every year – especially from small business sponsors who claim it is an unnecessary administrative burden.

The LVT scheme imposes regulatory burden on sponsors of therapeutic goods. Consistent with the Government's agenda to reduce red tape, the TGA undertook a policy and operational review of the LVT scheme. Before a decision about the future operation or the cessation of the LVT scheme is made, the essential questions to be considered include:

- Is there a contemporary need for an LVT scheme?
- Is there a problem to be solved by an LVT scheme?
- Are there other options available to address the needs of businesses?

What policy options are being considered?

The framework in which the TGA must consider proposed policy options includes:

1. That the policy is consistent with the objectives of the Act
2. That those who create a need to regulate bear the cost of regulation and the scheme is compliant with the Cost Recovery Guidelines
3. The proposed scheme is not inconsistent with the aims of the National Medicines Policy[8]
4. The total costs of specified pre and post market functions are appropriately recovered through annual charges
5. That it simplifies the administrative processes and its effectiveness; and
6. That it should reduce regulatory burden on industry.

Regulatory options

Option 1: status quo - retain the LVT scheme

This option would involve no change to current arrangements. The scheme would continue in its current form.

The costs to the businesses which cross subsidise the LVT scheme, and costs to the Government to manage the scheme, will continue to increase over time, while not meeting the intended purpose of the scheme.

Option 2: replace the LVT scheme with one that only grants exemptions for register entries which are yet to commence turnover

The second viable option that was considered was to deregulate the criteria for eligibility of the LVT scheme to only those Register entries which are yet to commence turnover.

Option 3: cease the scheme

This non-regulatory option would involve the complete cessation of the LVT scheme.

RIS development

The following are the major decision points leading up to the development of the LVT RIS.

- In July 2012, the TGA released a plan for delivering reforms which were intended to:
  - deliver outcomes that responded to the (then) Government's recommendations
  - achieve operational reforms needed to deliver benefits from those recommendations; and
  - ensure that concurrent reform activities underway at the TGA in addition to the reforms were achieved in a coordinated way.

[8] National Medicines Policy <http://www.health.gov.au/internet/main/publishing.nsf/Content/National+Medicines+Policy-1>

- The plan included a range of governance and related reform projects including the operational and policy review of the low value turnover exemption scheme.
- The review of the LVT scheme commenced in 2013 and the initial findings from the review were subsequently used to inform and develop a *Review of the low value turnover exemption scheme consultation paper* which was issued for public consultation on the TGA website on 10 April 2014 (closing on 23 May 2014). The purpose of the consultation paper was to seek stakeholders views on the following essential questions, before a decision about the operation or the cessation of the LVT scheme was made:
  a. Is there a contemporary need for an LVT scheme?
  b. Is there a problem to be solved by an LVT scheme?
  c. Are there other options available to address the needs of businesses.
- Submissions received in response to the public consultation were used to prioritise and short-list the regulatory options for inclusion in developing the LVT RIS
- In July 2014, the Office of Best Practice Regulation (OBPR), after considering the TGA's preliminary assessment, advised that a decision RIS was required. They also advised that consultation undertaken by the TGA was considered to be adequate
- The draft LVT RIS responding to the all seven RIS questions was developed out of the initial review and subsequent consultation with industry bodies and working groups and was then sent to the OBPR for First Pass Final Assessment in February 2015
- The OBPR provided feedback on the draft RIS and their suggestions were incorporated into the final RIS to ensure that all seven RIS questions were answered in full
- Second Pass Final Assessment was sought from the OBPR in March 2015.

Consultation options not assessed in RIS

The "Review of the low value turnover exemption scheme" consultation paper was released publicly on 10 April 2014. The paper put forward five options to reform the LVT scheme. Following the conclusion of the public consultation [on 23 May 2014], an initial assessment of the submissions received identified that:

- Consultation Option 3 *"Replace the LVT scheme with one that only grants exemptions for Register entries which are not supplied to the Australian market"* in combination of some features included in option 2; and consultation Option 5 "Cease the LVT scheme completely" were each considered to be feasible options for achieving the Government's objectives of reducing red tape and regulatory burden.
  - The impacts of consultation options 3 and 5, together with the impact of maintaining the status quo as detailed in consultation Option 1 *"Retain the LVT scheme in its current form"*, are all further assessed in this RIS
- RIS Option 2 is a composite of consultation Option 2 and consultation Option 3. Consultation Option 2 *"Retain the LVT scheme with some amendments"* **on its own** was not considered a feasible option for achieving the Government's objectives because,
  - implementation of Option 2 would not address cost recovery compliance issues arising from the current LVT scheme
  - participation requirements for the LVT scheme would continue to be overly complex and convoluted, particularly for businesses (e.g. small businesses) who may not have

the required financial or regulatory resources available to participate in the scheme; and

- the administrative burden would not sufficiently decrease for industry thus missing the point on red tape reduction objectives of Government.

Note. Deregulatory elements of consultation Option 2 which were favourably received in the public consultation (such as the TGA should accept self-declaration, rather than third party certification, of turnover) were adopted into the RIS Option 2 *"Replace the LVT scheme with one that only grants exemptions for Register entries which are yet to commence turnover"*. Consultation Option 4 *"Replace the LVT scheme with one that only grants exemptions for Register entries where the sponsor is a small business"* was likewise not considered to be a feasible option for achieving the Government's objectives. The impacts of consultation Option 4 were not further assessed in this RIS because:

- Limiting the LVT scheme to small businesses (only) may force companies that do not meet the criterion [of small business] to remove products from the Register which are either not currently supplied to the Australian market or would not be viable to supply if an annual charge is levied. This could create a public health risk by compromising patients' ready access to essential or unique therapeutic goods
- Allowing the LVT exemption to small business, without any regard to turnover of their products, would make the scheme inconsistent with the Policy and Cost Recovery Guidelines.
- There was very low support of the proposal to limit access to the LVT scheme to small businesses
- Under the current scheme small business receive a very small proportion of the total LVT benefit
- One industry association suggested that if government wishes to support small to medium enterprises in the therapeutic goods sector then this would more appropriately be done though an industry assistance scheme via the Department of Industry and Science.

What is the likely benefit of each option?

Option 1: status quo - retain the LVT scheme

Concerns around the current LVT scheme, outlined in this paper, include ineffectiveness in meeting its original objectives, inequity, administrative burden and inconsistency with the Cost Recovery Guidelines. Whilst it is noted that there is a widespread use of the scheme, given the problems described with the current LVT scheme in achieving the original policy objective, continuation of the scheme in its current form is not considered to be viable.

Importantly, the status quo will not address any of the issues for small businesses who will likely continue to be under-represented beneficiaries of the LVT scheme.

Option 2: replace the LVT scheme with one that only grants exemptions for Register entries which are $0 turnover entries

Under this option, a sponsor of a Register entry that has not commenced generating turnover would be exempt from the requirement to pay an annual charge in respect of that entry, up until the first year that turnover occurs. The annual charge would then apply to the entry until it was removed from the Register. Unlike the current LVT scheme, it would apply to biologicals as well

as all other therapeutic goods on the Register.The rationale for this option is that, as these products covered by the entry[9] have not yet generated turnover, they require minimal post-market surveillance and monitoring by the TGA. For example, if a product has not commenced sales in Australia, the TGA is not required to undertake pharmacovigilance activities related to domestic recalls; product testing or adverse drug reactions for the vast majority of these products [however must retain the capacity to do so].

While we recognise that pharmacovigilance requirements apply after a product is first supplied (which could feasibly be earlier than when the product starts generating turnover), our assessment is that most products would generate turnover at the same time as they commence supply. Accordingly, no significant issue would arise from a cost recovery perspective as there are minimal administrative costs in relation to maintaining the entry on the Register until the entry is generating turnover. This would better align with the principles of cost recovery.

Under this option, all Register entries which have commenced generating turnover (and which are therefore subject to post market monitoring and compliance) would be levied an annual charge until they are removed from the Register, resulting in potential decreases in some charges.

Although several submissions to the public consultation did not explicitly support a single model among those proposed for discussion, most submissions supported amendments to the LVT Scheme and/or a scheme wherein exemptions from TGA annual charges be granted to those therapeutic goods which had not been supplied to the Australian market. The argument in favour of this option was that the TGA doesn't incur post market costs (through medicines and devices vigilance programs) unless and until products are supplied to the market and therefore an annual charge should not be levied on such products before that time.

Several submissions proposed that a self-declaration of sales turnover of a product seeking exemption, (rather than a statement of turnover certified by a third party accountant) should be sufficient for confirming a products' eligibility for an exemption. The submissions acknowledged that a move to self-declaration would need to be complemented by an audit program by the TGA to deter and identify any undesired behaviour.

This option would better align the operation of the scheme with the Cost Recovery Guidelines, as those who create the need for post market activities would bear the costs of such activities, whilst still providing some relief to sponsors who have products which are yet to generate turnover.

This option would provide administrative improvements to the scheme such as enabling sponsors to self-declare that a product had $0 turnover in a financial year and thus qualify for a 'low value turnover' (LVT) exemption, rather than requiring a declaration from an independent accountant. Random and/or targeted audits by the TGA would be carried out to detect incorrect declarations. A challenge of the current LVT scheme is that as part of the application and validation process, sponsors are required to provide the TGA with the actual turnover of each entry in respect of which an LVT exemption is claimed, though most businesses wouldn't normally capture and report this information (i.e. by reference to a particular product). Under this option, sponsors will be in a better position to make this declaration.

It is estimated that approximately 74% of the Register entries which are expected to be exempted under the LVT scheme in 2014-15 would continue to be exempted under this model up until first turnover.

Given that annual charges would be paid across a broader number of Register entries, it is expected that under this option, the annual charge for some entries on the Register would be

[9] Entries for certain classes of medical devices can cover more than medical device provided they are the same kind of medical device.

reduced. However, some sponsors may choose to cancel some entries on the Register where they are no longer eligible for the exemption where, for instance they now must pay charges but the turnover is low.

Our assessment of entries subject to LVT exemption was that most are readily available with the same active ingredient from multiple sponsors in the Australian market. If the removal of a unique product from the Register by a sponsor did occur as a result of this change, and no alternative product was readily available in the Australian market, patient access to such products could continue via other regulatory schemes such as the Special Access and Authorised Prescriber Schemes. Additionally, the TGA will seek powers to waive the annual charge on the basis of the interests of public health, to avoid essential medicines and medical devices being removed from the Register if the sponsor is not likely to continue their supply if an annual charge were to apply.

As the proposed approach relies, more than the current LVT scheme, on sponsors to provide us with accurate and timely information (particularly about when goods first generate turnover), an audit program would be developed to check and/or detect any deliberately or inadvertently incorrect declarations for claiming annual charge exemptions. This would include situations where TGA becomes aware that a product is being supplied, however no notification of turnover has been provided by the sponsor and no annual charge has been paid.

Sponsors will be routinely reminded through the TGA website and the sponsor online service portal to ensure their annual declaration of LVT is made on time if the exemption is to be maintained. Moreover, it would be an offence under the Commonwealth Criminal Code to make a false declaration. Sponsors will also be encouraged to provide accurate and timely disclosure of their product turnover through penalties which will apply for false declarations. Penalty provisions in the Regulations already allow for sponsors to be penalised 10 penalty units [where each penalty point equals $170] for each false declaration; and, as the maximum 10 point penalty may not be sufficient to deter a false declaration on a higher cost annual charge (for example, a biological prescription medicine annual charge which is $6,585), we are proposing that the exemption(s) for any affected entries would be cancelled back to the date of entry and the applicable annual charges would become **payable from the date of entry on the Register *or* the date of commencement of the scheme, whichever is later even if there is evidence of $0 turnover (again) in subsequent years.**

Existing Therapeutic Goods Act provisions in section 31 (in relation to listed and registered goods), section 32JA (in relation to biologicals) and section 42JA (in relation to medical devices) enable the making of regulations to authorise the Secretary to require sponsors, at any time, to provide information about the turnover of goods for the purpose of administering the exemption scheme. It is proposed that such regulations will be enacted as part of the new scheme. The regulations will also utilise existing offence provisions under those sections if the sponsor fails to respond to such a request or provides information that is false or misleading in a material particular. Such information would be sought by the Secretary to ascertain whether any turnover had been generated. Failing to respond to such a request would also be grounds for suspending or cancelling the relevant entry from the Register.

The cost of audit is estimated to be $0.420 million in year one.

This option has the following benefits:

- Around 74% of current exemptions would be expected to continue (on the basis of our review of those exemptions that were granted exemption with $0 turnover under the LVT scheme) up until first turnover
- Administrative processes would be simpler as sponsors would only be required to provide a self-declaration of '$0 turnover' to confirm the exemption from annual charges. This will particularly assist sponsors (for example small business sponsors) who may not have dedicated regulatory compliance officers or qualified accountants

  - We have anecdotal information (arising from comments in consultation submissions) that there is likely to be a cohort of small and medium business sponsors who will participate in the exemption scheme for the first time due to the reduced administrative requirements of the proposed scheme.

- The annual charge for some Register entries would be reduced
- Resetting annual charges to differentiate between 'innovator' and 'generic' chemical prescription medicines will better reflect the difference in risk between the two types of products and recognise that there are multiple sponsors for generic products. In addition, it helps to mitigate the effects of the proposed changes on the sponsors of a range of low value turnover products which will no longer qualify for an exemption under a $0 turnover scheme
  - Full particulars of the proposal to reset chemical prescription medicines charges are detailed under ***'Other Amendments - Annual charges for prescription medicines (chemical medicines)'*** (RIS pages 28 to 30).
- The operation of the new scheme would be aligned with the Cost Recovery Guidelines, with a stronger relationship between those creating a need for post market regulatory activities and those paying for them
- This option would provide relief from TGA annual charges to sponsors (businesses) of all sizes until a good is generating turnover. Existing entries could likewise remain on the Register without any annual charge, until they are generating turnover
- Existing entries which are not generating turnover would remain on the Register without incurring annual charges resulting in a quicker time to market for those products
- A reduction in regulatory burden of an estimated $1.2 million is expected under this option. Businesses that would still be eligible for exemption would have decreased requirements, such as the removal of the requirement for verification of turnover by a third party accountant.

The disadvantages of this option include:

- Given that exemptions would apply on the basis of self-declarations by sponsors, an audit program to detect incorrect and false declarations would be required.
- The cost of compliance for industry would be higher than the cost under option 3 (discussed below)
- Small businesses that report low turnover of their products will not receive an exemption. However, current evidence indicates that small businesses are not the primary beneficiaries of the current scheme but they will benefit through reductions in annual charges, simplified administrative processes and reduction in overall burden.

Quantification of cost to business and the community

Regulatory burden and cost offset estimate table

The regulatory burden measures the costs for business to comply with new regulations and the savings involved in removing regulation. By decreasing the amount of exemptions, businesses will benefit from the reduction and cessation of administrative costs associated with applying for and verifying their eligibility for the scheme. The regulatory burden does not include direct costs such as fees and charges applicable to sponsors.

Average Annual Regulatory Costs (from Business as usual)				
Change in costs ($million)	**Business**	**Community Organisations**	**Individuals**	**Total change in cost**
Total by Sector	-$3.0	$	$	-$3.0
Cost offset ($million)	**Business**	**Community Organisations**	**Individuals**	**Total by Source**
[Offset proposal]				
Are all new costs offset? ☐ yes, costs are offset ☐ no, costs are not offset ☑ deregulatory, no offsets required				
Total (Change in costs - Cost offset) ($3.0 million)				

Assumptions

The costs were calculated by assessing the regulatory burden costs of the current scheme and comparing it to the regulatory burden costs that would be involved in the new scheme.

Proposed situation

- 3,679 sponsors incur annual product charges (on the next 1 July) for existing entries on the Register
- 1,560 sponsors incur annual product charges for new entries on the Register (new entries on or after 1 July in a financial year)
- 77,591 existing or new entries on the Register
- The TGA will initially identify all current entries which are likely to be eligible for LVT exemption (based on two previous year statements of actual turnover supplied in support of LVT applications for 2013-14 and 2014-15 and one declaration in relation to 2014-15 made after the new scheme commences). Sponsors will only receive an annual charge invoice for any entries which are non-LVT
- It takes one hour once a year for one staff member to organise and pay the invoice for non-LVT entries at a wage rate of $53.20 per hour
- 850 sponsors will renew their LVT rating with the TGA. This will take 4 hours at a wage rate of $72.80 per hour
- 20 sponsors will be selected for an audit each year. This will involve (including pre-audit preparation and on-site participation) three sponsor representatives /staff members (e.g. generally a Senior Regulatory Affairs Officer, Chief Financial Officer and/or Business Manager; and a Senior Management Accountant) for approximately 12 hours at a labour rate of $72.80 per hour /per staff member

- 850 sponsors will notify the commencement of turnover (this is a voluntary option). This will be done 4 times per year, involve one staff member working for 4 hours at a wage rate of $53.20
- 850 sponsors will organise to pay the product charge 4 times per year, involving one staff member at a pay rate of $53.20 per hour.

Deregulatory steps

- 2,829 businesses with existing entries will no longer need to assess actual turnover at the end of the financial year. This task requires 8 hours of staff time at a pay rate of $72.80 per hour
- 850 sponsors with existing entries will no longer be required to prepare an existing entry LVT application, taking 8 hours of staff time at $72.80 per hour
- 1,225 businesses with new entries will no longer need to assess whether the estimated turnover of their new entries will be a low value turnover (for subsequent making of an application for a new entry for the LVT scheme). This would involve one staff member working for one hour 12 times per annum at a wage rate of $72.80
- 335 businesses with new entries will no longer need to estimate their turnover three times per year when applying for the LVT scheme for the first time for one hour at a wage rate of $72.80 per hour
- 335 companies with new entries will no longer need to submit an LVT application and fee for a new entry which will entail one hour of staff time at a wage rate of $53.20 per hour.

Option 3: cease the scheme completely

Under this option, it is expected that most sponsors would benefit from decreases in annual charge rates.

In the short term, sponsors could be adversely affected by the cessation of the scheme, as they would be required to pay annual charges for all Register entries for which they are responsible.

Although cessation of the LVT scheme would result in a reduction in the rates of annual charges and remove regulatory burden, there was limited support during consultation for the complete cessation of the scheme. It was commented that discontinuation of the scheme may force companies to remove some of their products from the Register which would not be commercially viable to supply if an annual charge is levied.

Therefore an important consideration of this option would be the expected cancellation by sponsors of some entries. If a unique product was removed from the Register by a sponsor as a result of this change, and no alternative product was available in the Australian market, patient access to such products could continue via the Special Access or Authorised Prescriber Schemes, however this would be a shift in regulatory burden rather than a reduction.

The variability currently associated with forecasting revenue due to LVT exemptions, and therefore the difficulty in setting annual charge rates, would be eliminated, improving TGA's ability to forecast revenue and tie charges to operational costs. This would also assist sponsors with their budget planning providing a lot more certainty and predictability around annual charges.

As the costs of post market functions would be recovered across all products (based on product risk), the cost recovery arrangements would be aligned with the Cost Recovery Guidelines.

It is recognised that the following impacts may arise if this option were implemented:

- Some sponsors may choose to cancel Register entries with low or $0 turnover, possibly resulting in the removal of some therapeutic goods from the Australian market
- There will be no separate relief from the cost of regulation for small business or in relation to new therapeutic goods entering the market (which may, initially, have $0 turnover) however, there is evidence to suggest that small businesses are not the primary beneficiaries of the current scheme and may in fact benefit from lower annual charges
- Low volume unique products (e.g. for rare or unique medical conditions) sponsored by larger business will no longer be exempt from annual charges
- Sponsors would be dissuaded from applying for regulatory approval for therapeutic goods unless and until they were likely to produce some compensating turnover. This could result in delayed access for consumers and patients.

The complete cessation of the scheme would adversely impact small business as there would be no relief from annual charges until their products are supplied to the market. Additionally, on some occasions, the lag time between registration of the product and its launch in the market could be longer than what small businesses could afford.

Quantification of cost to business and the community

Regulatory Burden and Cost Offset Estimate Table

Average Annual Regulatory Costs (from Business as usual)				
Change in costs ($million)	**Business**	**Community Organisations**	**Individuals**	**Total change in cost**
Total by Sector	-$3.4	$	$	-$3.4
Cost offset ($million)	**Business**	**Community Organisations**	**Individuals**	**Total by Source**
[Offset proposal]				
Are all new costs offset? ☐ yes, costs are offset ☐ no, costs are not offset ☑ deregulatory, no offsets required				
Total (Change in costs - Cost offset) ($3.4 million)				

Assumptions

The deregulatory component will be identical to Option 2, while the regulatory component will affect all 3,679 sponsors who will pay their invoices. This will take administrative staff 1 hour on four occasions per year at a rate of $53.20/hour.

Who was consulted about the options and how?

On 10 April 2014, the TGA issued the **'Review of Low Value Turnover Exemption Scheme'** consultation paper through its website for consultation with sponsors and other interested parties on the future operation of the scheme. In addition, the TGA wrote to peak therapeutic industry associations asking them to bring this consultation paper to the attention of their members and encouraged them to provide submissions. The six week consultation period ended on 23 May 2014.

The options for the future operation of the LVT scheme that were presented with an invitation for comments from sponsors and other interested parties were:

Option 1: Retain the LVT scheme in its current form.

Option 2: Retain the LVT scheme, with some amendments to improve its efficiency.

Option 3: Replace the LVT scheme with one that only grants exemptions for Register entries that are not supplied to the Australian market.

Option 4: Replace the LVT scheme with one that only grants exemptions for Register entries where the sponsor is a small business.

Option 5: Cease the LVT scheme completely.

In response, the TGA received 44 submissions: 35 from sponsors; and 9 from peak industry bodies. The submissions were published on the TGA website.

Almost all submissions commented that the current LVT scheme was complex and administratively burdensome and that it was not desirable to continue the scheme in its current form. Some sponsors, through their peak bodies, stated that due to the administrative costs of preparing and submitting an LVT exemption application they do not take advantage of the LVT scheme. Most submissions supported change to the current LVT scheme.

Although several submissions did not explicitly support a single model among those proposed, most submissions supported amendments to the LVT scheme and/or a scheme wherein exemptions from TGA annual charges be granted to those therapeutic goods which are not supplied to the market. The argument in favour of the latter option was that the TGA doesn't incur post market costs (through medicines and devices vigilance programs) where products are not supplied to the market and therefore an annual charge should not be levied on such products.

Several submissions proposed that a self-declaration of sales turnover, or alternatively non-supply of a product seeking exemption, (rather than the one certified by a third party accountant) should be sufficient for seeking an exemption and may be complemented by random audits. This view is reflected in Option 2. Additionally, Option 2 is compliant with the Cost Recovery Guidelines and will minimise administrative burden for industry.

Although cessation of the scheme would potentially result in a greater reduction of the rates of annual charges, there was limited support for this option. It was commented that discontinuation of the LVT scheme may force companies to remove some of their products from the Register which are either not currently supplied to the Australian market or would not be viable to supply if an annual charge is levied.

One industry association suggested that if government wishes to support small to medium enterprises in the therapeutic goods sector then this would more appropriately be done though an industry assistance scheme via the Department of Industry. Government support schemes such as those offered through the Department of Industry to small business provide assistance or incentives for small and medium enterprises to enter the market. The current LVT scheme

provides relief from annual charges for products with low or $0 turnover but does not impact on the cost of bringing products to the market.

What is the best option from those considered?

The current LVT scheme (option 1) is not achieving its intended objectives. Apart from the cost it places on businesses the LVT scheme is inconsistent with Government policy as it is administratively difficult for both TGA and business to administer.

Implementation of option 2 would reduce administrative burden to industry. The Scheme's exemption would operate on the basis of a declaration of $0 turnover by the sponsor of therapeutic goods, rather than a third party accountant certification of annual turnover as exists under the current LVT scheme. There would be no requirement to make an application or pay an application fee for seeking exemption. A decision to approve the exemption by a delegate of the Secretary would not be required. This would remove administrative complexities for both sponsors and the TGA, reducing regulatory burden for industry.

Given that exemptions would apply on the basis of (at least annual) self-declarations by sponsors, an audit program to detect incorrect declarations would be undertaken.

Implementation of option 3 would result in a further administrative saving to industry when compared with option 1 and 2 respectively.

While implementation of option 3 would result in maximum saving in administrative burden, it is likely that the number of products which would be cancelled from the Register would be significantly higher than the number of products to be cancelled under option 2 and access to new therapeutic goods may be delayed. This could compromise the timely access of essential therapeutic goods to patients and pose a risk to public health.

In view of the above, the implementation of option 2 is the preferred option from the other two options discussed above. Implementation of the proposed option would be consistent with the framework in which a scheme is being considered:

1. The scheme would be consistent with the objectives of the Act
2. Those who create a need to regulate bear the cost of regulation and the scheme would be compliant with the Cost Recovery Guidelines
3. The scheme would not be inconsistent with the aims of the National Medicines Policy[10]
4. The total costs of specified pre and post market functions would be recovered through annual charges
5. It would simplify the administrative processes and improve its effectiveness
6. It would reduce regulatory burden on industry
7. It would not place undue risk on access to therapeutic goods by consumers.

[10] National Medicines Policy
<http://www.health.gov.au/internet/main/publishing.nsf/Content/National+Medicines+Policy-1>

Other amendments

Annual charges

This section deals with the impact of the review of the low value turnover (LVT) exemption scheme on the rates of annual charges. The rates of annual charges are calculated by dividing the total costs to be recovered through annual charges for each industry sector and product class by the total number of entries for that product class on the Register, excluding the number of entries likely to be exempted from annual charges.

In order to ensure full cost recovery of post-market functions, the rates of annual charges are set taking into consideration the value of the exemptions to be granted in a financial year (50% in 2013-14 and increasing each year as take up of the scheme increases, thereby putting pressure on increases to the rates of annual charges). For example, in 2013-14, 3,679 sponsors were invoiced for annual charges relating to 77,591 Register entries - totalling $100.5 million. Of these, 1,001 sponsors applied for, and received, LVT exemptions (relating to 21,830 Register entries), totalling $49.9 million. The exemptions resulted in net annual charge revenue of $50.5 million – only 50.3% of the invoiced annual charges in that year.

For 2014-15, we have budgeted annual charges revenue of $54.2 million from 57,618 Register entries, after allowing for LVT exemptions of $55.8m from 24,439 entries. From 1 July 2015, the current LVT scheme is expected to be replaced with a new scheme under which exemption will be given to those Register entries which have $0 turnover. It is expected that around 74% of the current LVT exempted entries would be exempt under the new scheme as those entries have $0 turnover. As annual charges would be paid across a broader number of Register entries the rates of annual charge for some Register entries would be reduced for 2015-16. It is likely that some sponsors would choose to cancel some entries on the Register where they are no longer eligible for the exemption. While the potential decreases in the rates of annual charge are dependent on how many entries are cancelled by sponsors (and therefore no longer pay annual charges), withdrawal rates are likely to vary from sponsor to sponsor based on individual commercial decisions. However for the purpose of revenue forecasting and setting the rates for 2015-16 we have assumed a withdrawal rate of 50% of currently exempted entries which will no longer qualify for an exemption under the proposed scheme.

Annual charges for prescription medicines (chemical medicines)

Different levels of charges have been set for different classes of therapeutic goods to reflect the differing levels of risk.

For example, annual charges increase with the class of medical device from $80 for class I devices to $1,210 for class III and AIMD devices. Similarly with medicines, there are different annual charges for listed medicines, registered OTC medicines, biological prescription medicines and non-biological (chemical) prescription medicines. However, the current scheme does not differentiate charges for new chemical prescription medicines and those which have been in the market for some time, and are thus off patent and are generic chemical prescription medicines.

The significant difference in annual charges for chemical prescription medicines[11] ($3,955) and biological prescription medicines[12] ($6,585), represents the difference in the level of pharmacovigilance required for the biological products and potentially higher costs (e.g. in laboratory analysis of this class of products).

[11] Prescription Medicines - Non-Biologics
[12] Prescription Medicines - Biologics

Some studies have shown that there is a heightened risk of adverse events from biologics compared with other prescription medicines, however, the annual charges for 'innovator' or recent to market chemical prescription medicines and generic medicines, which are based on out-of-patent substances which have been in the market usually for some years, are currently the same.

While recognising that the setting of charges to reflect the potential risk of a class of therapeutic goods is an inexact science, in consultations on the reform of TGA annual charges (through these proposed changes to the LVT scheme), TGA was asked to review the levels of charges for generic chemical prescription medicines for a number of reasons:

- There is evidence from a number of sources that many safety / post-market issues arise in the first few years of marketing, as their use changes from being in the clinical trials participants used to support registration (small defined populations free of co-morbidities) to the wider public post-market approval
- TGA undertakes additional pharmacovigilance activities for new prescription medicines. This includes the development and agreement of a Risk Management Plan, together with annual Periodic Safety Update Reports (PSURs). Since 2010, TGA has not required PSURs for generic chemical prescription medicines
- Increased monitoring of new products (relative to established and generic medicines) will be required as more therapies are introduced globally through accelerated or provisional approval processes, often with greater emphasis on the limited data from early stage clinical trials. Several US studies have proposed that the greater use of accelerated review processes by FDA for new prescription medicines has led to more products with safety issues, although increased emphasis in recent years on pharmacovigilance by regulators globally will also contribute to more safety issues having been identified
- In addition, because we charge the annual charge on a 'per ARTG entry' model, and that there are usually several generic versions of each out-of-patent medicine on the Register, we are potentially recovering more in annual charges in aggregate for many generic medicine substances than comparable new chemical entity (NCE) substances.

In view of the above it is proposed to introduce a separate rate of annual charge for Register entries for generic chemical prescription medicines which will be lower than the rate for the Register entries for the innovator product. However, once a generic product is registered on the Register the innovator product would also pay the lower charge applicable to the generic version. It is anticipated that the maximum period that a chemical medicine in any particular entry would be at the higher annual charge would be 12 years (subject to the approval of new indications that were included in the entry). This would be applicable for instance if no generic was ever registered for a particular medicine.

The below table includes the proposed rates of annual charges, expected number of entries paying annual charges and annual charges revenue forecast for 2015-16.

Table 5 Proposed reductions in annual charges, rates of annual charges and revenue forecast for 2015-16

Revenue	2014-15 annual charge $	Expected entries paying annual charges Units	Proposed reduction in annual charges %	New rate $	Projected revenue $
Prescription Medicines - Biologics	6,585	504	-	6,585	3,319,485
Prescription Medicines - Non -Biologics (Innovators)	3,955	1,614	5	3,760	6,067,283
Prescription Medicines - Non -Biologics (generics)	3,955	4,149	23	3,050	12,655,542
Registered Medicines (Other than S4&S8) Annual Charge	1,350	2,356	-	1,350	3,180,784
Complementary Medicines	965	9,937	-	965	9,589,028
Device Class AIMD Annual Charge	1,210	346	5	1,150	397,987
Device Class III Annual Charge	1,210	2,589	5	1,150	2,977,221
Device Class IIb Annual Charge	940	5,156	5	890	4,588,449
Device Class IIa Annual Charge	940	9,462	5	890	8,420,956
Device Class 1 Sterile Annual Charge	615	1,858	-	615	1,142,911
Device Class 1 Measuring Annual Charge	615	385	-	615	237,029
Device Class 1 Annual Charge	80	21,962	-	80	1,756,949
Listed Devices Annual Charge	1,350	22	-	1,350	30,301
Listed Devices Annual Charge IVD, Tampons & Disinfectants	770	415	-	770	319,656
Registered Devices Annual Charge - IVD, Tampons & Disinfectants	1,515	53	-	1,520	80,603

Revenue	2014-15 annual charge $	Expected entries paying annual charges Units	Proposed reduction in annual charges %	New rate $	Projected revenue $
Registered Devices	2,650	7	-	2,650	19,139
		60,816			54,783,323

How will you implement and evaluate the chosen option?

If the recommendation to implement the proposed exemption scheme is approved, the Regulations and Charges Regulations will need to be amended. Section 44 of the Act allows for amending of regulations to exempt a sponsor from the liability to pay an annual charge so long as the turnover of an entry is $0.

Amendments to regulations to effect the changes will be prepared for consideration and approval by the Federal Executive Council (EXCO).

Sponsors and other stakeholders will be advised of amendments, including the revised rates of annual charges, through the TGA website and client service portal, sponsor notices, and advice to industry associations.

The date of commencement is proposed to coincide with the commencement of a financial year as this is the start of the annual charges and exemption cycle each year.

The client portal will be developed so that sponsors are able to provide their annual renewal declarations of $0 turnover, and notification of commencement of generating turnover (where they choose to do so), through the portal. This would be the most cost effective means for sponsors to meet their obligations under the proposed scheme, though a paper based option would also be implemented for those sponsors who choose not to use the electronic business system.

The TGA website will include a link to the amendments on Comlaw/FRLI, as well as extensive advice and information for stakeholders.

Annexure A - Legislative references

Therapeutic Goods Act 1989

44A Exemptions from liability to pay charges

Subsection 44A (1) states that the regulations may make provision for and in relation to:

a. exempting a person from liability to pay annual registration charge, annual listing charge or annual charge for inclusion in the Register for a financial year (the *current year*) if the person's turnover of the therapeutic goods concerned for the financial year specified in the regulations is of low value

b. the making of an application for an exemption and requiring payment of that charge for the current year if the application is refused and

c. cancelling an exemption and requiring payment of that charge for the current year.

Therapeutic Goods Regulations 1990 (current regime)[13]

Regulation 43AAB: definitions

Approved person

Approved person means a person who is a qualified accountant under section 88B of the *Corporations Act 2001*, but does not include:

- A person who is required to submit a statement signed by an approved person or
- An employee of that person.

Existing entry

Existing entry, for a therapeutic good means an entry for registration, listing or inclusion of the therapeutic good in the Register that is not a new entry.

Low value turnover (LVT)

Low value turnover means a turnover of not more than 15 times the annual registration charge, the annual listing charge, or the annual charge for inclusion in the Register (other than the annual charge for inclusion of a biological under Part 3-2A of the Act) payable for a financial year.

New entry

A new entry, for a therapeutic good means an entry for registration, listing or inclusion the therapeutic good in the Register that commenced in the financial year.

Turnover (Therapeutic Good)

The turnover for a therapeutic good is the gross dollar receipts (excluding GST) from sales of the therapeutic good in Australia for a financial year, including retail and wholesale sales.

[13] Note that the current LVT scheme does not apply to biologicals.

Regulation 43AAC: Application requirements

Subregulation 43AAC (1) states that for section 44A of the Act, the person liable to pay the annual registration charge, annual listing charge or the annual charge for inclusion of a therapeutic good in the Register can apply to the Secretary for an exemption from liability to pay the charge for the current financial year on the ground that the turnover of that good for the applicable financial year is a low value turnover.

Subregulation 43AAC (2) states that the application must be:

a. in writing, in a form approved by the Secretary; and

b. accompanied by:

   i. for an existing entry – a statement of actual turnover of the therapeutic good for the previous financial year, signed by an approved person; or

   ii. for a new entry – a statement of estimated turnover of the therapeutic good for the current financial year; and

   iii. subject to regulation 45A, the fee payable; and

c. received by the Secretary:

   i. for an existing entry – before 2 September of the financial year; and

   ii. for a new entry – at least 21 days before the date for payment of the charge mentioned in regulation 43AAA.

Subregulation 43AAC (3) states that the statements mentioned in subregulations 43AAC(2)(b)(i) and (ii) must be in a form approved by the Secretary.

Regulation 43AAD: Decision by the Secretary – exemption application

Subregulation 43AAD (1) states that within 21 days after receiving an application under subregulation 43AAC (1), the Secretary must:

a. decide whether to grant the exemption; and

b. give written notice to the person of the decision; and

c. if the decision is a refusal, the reasons for the decision.

Subregulation 43AAD (2) states that if the Secretary refuses to grant the exemption, the applicant must pay the charge for which exemption was sought:

a. for an existing entry – within the later of:

   i. 14 after the notice is given under subregulation 43AAD (1)(b); or

   ii. the date mentioned in paragraph 44 (1)(b) of the Act[14]; and

b. for a new entry – within the later of:

   i. 14 days after the notice is given under subregulation 43AAD (1) (b); or

   ii. The date mentioned in regulation 43AAA[15].

[14] This is 1 October.

[15] This is the last day of the second month after the month when the goods were entered in the Register.

Regulation 43AAE: Actual turnover – new entries in the Register

Subregulation 43AAE (1) requires that if an exemption has been granted under sub regulation 43AAD (1) for a new entry in the Register based on the estimated turnover of a therapeutic good for a financial year (the ***current year***), the person must give to the Secretary by 1 September in the following financial year (the ***following year***):

a. details, in writing in a form approved by the Secretary, of the actual turnover of the therapeutic goods for the current year; and

b. a statement, signed by an approved person, in a form approved by the Secretary, of the actual turnover of the therapeutic good for the current year.

Note. If the current year is financial year 2013-14, the following year is financial year 2014-15. The statement, signed by an approved person, detailing the actual turnover of the new entry in 2013-14 would therefore need to be received by 1 September 2014.

Subregulation 43AAE (2) states that before 1 September in the following year, the person may apply in writing for, and the Secretary may agree to, an extension of up to 28 days after the time mentioned in Regulation 43AAE (1) for giving the information.

Subregulation 43AAE (3) states that if the person does not give the information to the Secretary within the time mentioned in Regulation 43AAE (1) or within the extended time agreed to by the Secretary under Regulation 43AAE (2):

a. the exemption is taken to be cancelled on 30 September in the following year; and

b. the person must pay the charge for which the exemption was granted by 31 October of the following year.

Regulation 43AAF: Decision based on actual turnover

Subregulation 43AAF (1) states that the Secretary must within 21 days after receiving the information from a person under subregulation 43AAE (1):

a. decide whether the actual turnover of the therapeutic goods was low value; and

b. give the person notice of:

   i. the decision; and

   ii. if the decision is that the actual turnover was not a low value turnover – the reasons for the decision.

Subregulation 43AAF (2) states that if the Secretary decides that the turnover of the therapeutic good for the financial year was not a low value turnover and gives the person a notice under subregulation 43AAF (1) (b), then:

a. the exemption is cancelled; and

b. the person who receives the notice mentioned in subregulation 43AAF (1) (b) must pay the charge for which that exemption had been granted by 31 October of the following year.

Annexure B – Regulatory burden measure

Assumptions

Option 1 - new register entries

(average 3 actions [MONTHLY INVOICES] per sponsor per year)

Step No.	Description	TGA task	Sponsor task	Sponsor time (hours)	No of Sponsors affected	Class	Sponsor hourly rate	Sponsor total cost
1	**A new therapeutic product is listed, registered or included on the Register. An ARTG number is assigned to the product**	Yes	No	0.00	1,560	Not Applicable - TGA Only	0.00	$0.00
2	The full year annual charge is incurred (per ARTG No.) effective from the date of listing, registration or inclusion on the Register	Yes	No	0.00		Not Applicable - TGA Only	0.00	$0.00
3	TGA Financial Services issues a tax invoice to the sponsor for the applicable annual charge	Yes	No	0.00	1,560	Not Applicable - TGA Only	0.00	$0.00
4	**Sponsor assesses that the estimated turnover of the new entry for the current financial year will not be a low value turnover. (average 7 new entries per sponsor)**	No	Yes	1.00	1,225	Managers (including accountants)	72.80	$72.80
5	Sponsor pays the annual charge for the entry. No further action is required.	No	Yes	1.00	1,225	Clerical and Administrative Workers	53.20	$53.20

Step No	Description	TGA task	Sponsor task	Sponsor time (hours)	No of Sponsors affected	Class	Sponsor hourly rate	Sponsor total cost
6	**Sponsor assesses that the estimated turnover of the new entry for the current financial year will be a low value turnover. (average 7 new entries per sponsor)**	No	Yes	1.00	335	Managers (including accountants)	72.80	$72.80
7	Sponsor prepares an LVT application for the new entry which must be accompanied by (a) a statement of the estimated turnover of the therapeutic good for the current financial year and signed by the person liable to pay the charge; and (b) payment for the LVT application fee.	No	Yes	4.00	335	Managers (including accountants)	72.80	$291.20
8	The sponsor submits the completed LVT application to the TGA. The application must be received at least 21 days before the date for payment of the applicable annual charge. There is no extension if the application is not made in time.	No	Yes	0.50	335	Clerical and Administrative Workers	53.20	$26.60
9	The TGA Delegate assesses the LVT application. If approved, a letter is issued to the sponsor with a credit note for the exempted charge. As a new entry LVT exemption, the approval is conditional that the sponsor must provide by 1 September in the following year, a statement, signed by an approved person, detailing the actual turnover of the entry in the year the entry was a new entry.	Yes	No	0.00		Not Applicable - TGA Only	0.00	$0.00
9.1	The sponsor LVT application is not received at least 21 days before the date for payment of the applicable annual charge. The LVT application cannot be approved (Return to step 5)	N/a	N/a	0.00		Not Applicable – TGA Only	0.00	$0.00

Step No.	Description	TGA Task	Sponsor Task	Sponsor time (hours)	No of Sponsors affected	Class	Sponsor hourly rate	Sponsor total cost
10	**Validation reviews of new entry LVT exemptions commences on 1 July in the following year. The validation review involves the TGA writing to all affected sponsors to remind them their obligations to supply a statement of actual turnover by 1 September.**	Yes	No	0.00		Not Applicable - TGA Only	0.00	$0.00
11	The sponsor extracts the actual turnover of the entry from (e.g.) their sales/ finance system and records it on a 'statement of actual turnover' form (approved by the Secretary) and then must have the actual turnover verified by an approved person. If satisfied, the approved person signs a declaration that the turnover reported is the actual turnover of the entry. The sponsor sends the completed statement to the TGA by 1 September 2014	No	Yes	8.00	335	Managers (including accountants)	72.80	$582.40
11.1	*The sponsor cannot supply a statement of actual turnover by 1 September and applies in writing for an extension (up to 28 days). If received before 1 September, the TGA approves the extension to 29 September (23 out of 334 sponsors (or 7%) applied for extensions in 13-14)*	*Yes*	*Yes*	*1.00*	*24*	*N/a – Non-compliance matter*	*n/a*	*n/a*
12	**The TGA Delegate assesses the actual turnover of the new entry was a low value turnover. The exemption is confirmed under regulation 43AAF.**	Yes	No	0.00	280	Not Applicable - TGA Only	0.00	$0.00
13	The sponsor is notified by the TGA in writing that the exemption is confirmed and no further action is required.	Yes	No	0.00		Not Applicable - TGA Only	0.00	$0.00

Step No.	Description	TGA task	Sponsor task	Sponsor time (hours)	No of Sponsors affected	Class	Sponsor hourly rate	Sponsor total cost
14	**The TGA Delegate assesses the actual turnover of the new entry was not a low value turnover (i.e. > 15 times the amount of the charge for that entry). The exemption is cancelled under regulation 43AAF.**	Yes	No	0.00		Not Applicable - TGA Only	0.00	$0.00
15	The sponsor is notified by the TGA in writing that the exemption is cancelled and the annual charge is (now) payable by 31 October. The sponsor pays the tax invoice for the annual charge.	Yes	Yes	1.00	45	Clerical and Administrative Workers	53.20	$53.20
16	**The sponsor does not supply the statement of actual turnover by 1 September. The exemption is cancelled under regulation 43AAE.**	Yes	No	0.00		Not Applicable - TGA Only	0.00	$0.00
17	The sponsor is notified in writing that the exemption is cancelled under regulation 43AAE for failure to give information and the annual charge is (now) payable by 31 October. The sponsor pays the tax invoice for the annual charge.	Yes	Yes	1.00	10	Clerical and Administrative Workers	53.20	$53.20

Option 1 - existing register entries (on the Register on 1 July each year)

(One action [ANNUAL INVOICE] per year)

Step No.	Description	TGA task	Sponsor task	Sponsor time (hours)	No of Sponsors affected	Class	Sponsor hourly rate	Sponsor total cost
1	**All existing entries on the Register on 1 July incur the applicable full year annual charge(s)**	Yes	No	0.00		Not Applicable - TGA Only	0.00	$0.00
2	TGA Financial Services issues a tax invoice to the sponsor for the applicable annual charge(s).	Yes	No	0.00	3,679	Not Applicable - TGA Only	0.00	$0.00
3	**Sponsor assesses that the actual turnover of the existing entry in the previous financial year was not a low value turnover (i.e. > 15 times the annual charge for the entry). (average 18 existing entries per sponsor)**	No	Yes	8.00	2,829	Managers (including accountants)	72.80	$582.40
4	Sponsor pays the annual charge(s) for any non-LVT entry/entries. No further action is required.	No	Yes	1.00	2,829	Clerical and Administrative Workers	53.20	$53.20
5	**Sponsor assesses that the actual turnover of the existing entry in the previous year was low value. The sponsor extracts the actual turnover of the entry from (e.g.) their sales/ finance system and records it on a 'statement of actual turnover' form (approved by the Secretary) and then must have the actual turnover verified by an approved person. If satisfied, the approved person signs a declaration that the turnover reported was the actual turnover of the entry. (average 18 existing entries per sponsor)**	No	Yes	8.00	850	Managers (including accountants)	72.80	$582.40

Step No.	Description	TGA task	Sponsor task	Sponsor time (hours)	No of Sponsors affected	Class	Sponsor hourly rate	Sponsor total cost
6	**Sponsor prepares an LVT application for the existing entry which must be accompanied by (a) the statement of the actual turnover, signed by an approved person, and (b) payment for the LVT application fee ($150 per entry in 12-13, to a maximum fee of $15,000 for 100 or more LVT exemptions).**	No	Yes	8.00	850	Managers (including accountants)	72.80	$582.40
7	The sponsor submits the completed LVT application to the TGA. The application must be received before 2 September. There is no extension if the application is not made in time.	No	Yes	1.00	850	Clerical and Administrative Workers	53.20	$53.20
7.1	The sponsors LVT application is not received before 2 September. The LVT application cannot be approved. (Go directly to Step 9)	N/a	N/a	0.00			0.00	$0.00
8	**The TGA Delegate assesses the LVT application. If approved, a letter is issued to the sponsor with a credit note for any exempted charge(s).**	Yes	No	0.00		Not Applicable - TGA Only	0.00	$0.00
9	**Sponsor pays the annual charge(s) for any non-LVT entry/entries. No further action is required.**	No	Yes	1.00	850	Clerical and Administrative Workers	53.20	$53.20

Option 2 - $0 turnover scheme – transitional entries

(One action [ANNUAL INVOICE] per year)

Step No.	Description	TGA Task	Sponsor Task	Sponsor time (hours)	No of Sponsors affected	Class	Sponsor hourly rate	Sponsor total cost
1	**TGA will identify all entries which may be eligible for an initial LVT Exemption** **Entries on the Register 1 July 2014** - To qualify for an LVT exemption, an entry which was listed, registered or included on the Register on 1 July 2014 must have been approved for LVT exemption in 2013-14 and 2014-15 and have had $0 value turnover. The LVT approvals in 2013-14 and 2014-15 were made on the basis of the sponsors statement(s) of actual turnover (SOAT), signed by an approved person (a third party accountant) of the entry in 2012-13 (for approval of the 2013-14 LVT exemption) and 2013-14 (for the approval of the 2014-15 LVT exemption). ***2012-13 and 2013-14 data arising from the 2013-14 and 2014-15 LVT exemption approvals has been collated/analysed, with all eligible (pre-1 July 2014) entries short-listed for automatic LVT exemption when the scheme commences on 1 July 2015.***	Yes	No	0.00	3,679	Not Applicable - TGA Only	0.00	$0.00

Step No.	Description	TGA task	Sponsor task	Sponsor time (hours)	No of Sponsors affected	Class	Sponsor hourly rate	Sponsor total cost
	LVT exemptions for 2015-16 for an entry will depend on the sponsor being able to make a declaration by 22 July 2016 of $0 turnover for the entry for both 2014-15 and 2015-16. If the sponsor cannot make either or both declarations then: • they will retain any exemption for 2014-15 • they will be required to pay the annual charge for 2015-16 • they will be invoiced for the annual charge for 2015-16. **Entries added to the Register between 1 May and 30 June 2015** An entry which is first registered, listed or included on the Register on or after 1 May and before 1 July 2015 will be deemed to have been entered on the Register on 1 July for the purposes of the LVT exemption scheme (and thus automatically qualify for LVT for 2015-16). In practice, we recognise the sponsor would have been required to apply for LVT (and pay the LVT application fee) for the 2014-15 annual charge by the time the LVT scheme terminates. Sponsors will still be required in the next annual cycle to declare $0 turnover for 2015-16 in order to retain the exemption for that financial year. **Deemed entries will qualify as eligible for LVT exemption until (a) the entry generates turnover and the sponsor notifies the TGA of that turnover; or (b) the LVT exemption is renewed (or cancelled) following the next annual (turnover status) renewal declaration which is due by 22 July in the next financial year (i.e. 22 July 2016)**							

Step No.	Description	TGA Task	Sponsor Task	Sponsor time (hours)	No of Sponsors affected	Class	Sponsor hourly rate	Sponsor total cost
2	**Transitional entry is not pre-qualified for exemption**: A full year annual product charge tax invoice will be issued for the current financial year at the end of July to sponsors who did not have an exemption for the previous year. The sponsor will be required to pay the invoice by 15 September.	Yes	No	0.00	2,829	Not Applicable - TGA Only	0.00	$0.00
3	The full year annual product charge for will be levied on 1 July each year thereafter until the entry is cancelled from the Register	N/a	N/a				0.00	$0.00
4	The sponsor pays the applicable product charge invoice. No further action is required until the next full year annual product charge is incurred.	No	Yes	1.00	2,829	Clerical and Administrative Workers	53.20	$53.20
5	**The sponsor of an essential good applies for a waiver** of the charge for that financial year on the basis that (a) it is in the interests of public health for the product to remain on the Register (b) it would be commercially unviable for the sponsor to be required to pay the for that financial year. The matters to be taken into account in assessing the public health interest include the population that use the relevant goods, the likelihood of the goods being available through alternative means if the entry was cancelled at the request of the sponsor, the clinical needs of the users and the goods and the reasonable availability of alternatives and any relevant health risks.	Yes	Yes	1.50	85	Managers (including accountants)	72.80	$109.20

Step No.	Description	TGA task	Sponsor task	Sponsor time (hours)	No of Sponsors affected	Class	Sponsor hourly rate	Sponsor total cost
6	**Transitional entry is pre-qualified for exemption:** The sponsor will not receive a tax invoice for any entries which are '$0 turnover'. The LVT exemption will remain in force until the sponsor subsequently notifies the TGA that the entry has commenced generating turnover or fails to make the sponsors' annual (turnover status) renewal declaration by 22 July in the next financial year.	No	Yes	1.00	850	Clerical and Administrative Workers	53.20	$53.20
7	**Sponsor annual (turnover status) renewal declaration** – all sponsors who were exempt from paying a charge for an entry in the previous financial year will be required to declare that the entry had '$0 turnover' in that year within 21 days from commencement of each subsequent financial year to ensure it retains its annual charge exemption for that previous year. If the sponsor does not make such a declaration, they will be invoiced for the charges for the previous financial year and also for the current year. Both amounts are payable by 15 September.	No	Yes	4.00	850	Managers (including accountants)	72.80	$291.20
8	**Audit and monitoring program of '$0 turnover' entries** (The program will seek to review 20% of sponsor claims annually (for 100% coverage of claims every five years). The desk top audit and monitoring will be used to identify and short-list sponsors for audit to verify the turnover status of $0 turnover. The TGA will exercise powers in the Regulations to require the sponsor to provide information about a sponsors' turnover for the purposes of the administration of the LVT scheme.	Yes	No	0.00	200	Not Applicable - TGA Only	0.00	$0.00

Step No.	Description	TGA Task	Sponsor Task	Sponsor time (hours)	No of Sponsors affected	Class	Sponsor hourly rate	Sponsor total cost
9	**Onsite audit of '$0 turnover' Entries** - The program will seek to conduct onsite audits with 2% of sponsors annually. Based on previous audit activity between 2007 and 2012, the costing assumes 3 Manager or equivalent sponsor participants in each audit.	Yes	Yes	12.00	20	Managers (including accountants)	72.80	$2,620.80
10	**Sponsor declaration of turnover** - upon receiving the sponsors' notification that an entry has commenced generating turnover, the annual product charge exemption will cease and the full year product charge will be levied for the year in which turnover was generated	Yes	No	0.00		Not Applicable - TGA Only	0.00	$0.00
11	**ANNUAL CHARGES INVOICING SCHEDULE** **Monthly invoices - $0 turnover entries generating turnover during a financial year** Tax invoices will be issued (monthly) after a sponsors voluntary notification (during the current financial year) that a $0 turnover entry has commenced generating turnover in that financial year. **Example (Monthly Invoices):** A $0 turnover entry commences generating turnover on 1 October. The sponsor notifies the TGA that the entry is now a non-LVT entry [Note. if the sponsor does not voluntarily notify the TGA of turnover during the year, the sponsor will be invoiced for the year when the sponsor does not make a $0 turnover declaration due by 22 July in the next financial year].	Yes	No	0.00		Not Applicable - TGA Only	0.00	$0.00

Step No.	Description	TGA task	Sponsor task	Sponsor time (hours)	No of Sponsors affected	Class	Sponsor hourly rate	Sponsor total cost
	Where a sponsor notification of turnover is received during a financial year (i.e. at any other time than a compulsory annual (turnover status) renewal declaration by 22 July in the next financial year), an invoice for the applicable full year annual charge will be issued in the next monthly invoice run. ***If a compulsory annual (turnover status) renewal declaration of $0 turnover is not lodged with the TGA by 22 July in the next financial year, it will be assumed that the entry was non-LVT in the previous financial year and the applicable annual charge will become payable for that year together with the charge for the current year. Both will be payable by 15 September.*** **Annual invoicing 'Non-LVT entries'- Entries which are non-LVT on the next 1 July incur the full year annual charge. Annual invoices are issued in July for payment by 15 September (and again each year thereafter until the entry is cancelled from the Register).**							
12	**Sponsor pays the applicable annual product charge invoice.** No further action is required until the next full year annual product charge is incurred.	No	Yes	1.00	850	Clerical and Administrative Workers	53.20	$53.20

Option 2 - $0 turnover scheme – new entries

(Up to four actions [MONTHLY INVOICE(S)] per year)

Step No.	Description	TGA Task	Sponsor Task	Sponsor time (hours)	No of Sponsors affected	Class	Sponsor hourly rate	Sponsor total cost
	A new therapeutic product is listed, registered or included on the Register. An ARTG number is assigned to the product	Yes	No	0.00	1,560	Not Applicable - TGA Only	0.00	$0.00
	A new entry on the Register (on or after 1 July 2015) will be classified as LVT until the sponsor declares otherwise through the online portal or by paper form. (average 6 new entries per sponsor)	Yes	No	0.00	0	Not Applicable - TGA Only	0.00	$0.00
	When an entry is becomes a non-LVT entry, the full year annual charge is incurred (per ARTG No.) effective from the financial year when turnover was generated	No	Yes	1.00	1,225	Managers (including accountants)	72.80	$72.80
	TGA Financial Services issues a tax invoice to the sponsor for the applicable annual charge	Yes	No	0.00		Not Applicable - TGA Only	0.00	$0.00
	Sponsor pays the annual charge for the entry. No further action is required.	No	Yes	1.00	1,225	Clerical and Administrative Workers	53.20	$53.20

Step No.	Description	TGA task	Sponsor task	Sponsor time (hours)	No of Sponsors affected	Class	Sponsor hourly rate	Sponsor total cost
	Sponsor assesses that the turnover of a new entry is $0 turnover. (average 7 new entries per sponsor) No action is required by the sponsor of the new entry until (a) the entry commences generating turnover or (b) the next annual (turnover status) renewal declaration of $0 turnover is required (by 22 July in the next financial year). The LVT exemption will remain in force for an entry until the sponsor subsequently notifies the TGA that the entry has incurred turnover (subject to the sponsors' annual declaration [detailed below] within 21 days of commencement of the next financial year that an entry did not generate any turnover in the previous year and therefore continues to be eligible for an LVT exemption).	No	Yes	1.00	335	Managers (including accountants)	72.80	$72.80
	Sponsor provides an annual (turnover status) renewal declaration – In order to maintain an LVT exemption for an entry, the sponsor will be required to complete an online declaration that the entry did not generate turnover in the previous financial year by 22 July. If such a declaration is made, no further action is required until the next annual update is required (the next financial year) or the TGA is notified of turnover (whichever comes first).	No	Yes	1.00	335	Managers (including accountants)	72.80	$72.80
	Sponsor does not provide an annual (turnover status) renewal declaration - If a sponsor fails to provide a $0 turnover declaration by 22 July in the next financial year, the annual charge exemption will cease and the applicable annual product charge will be payable in relation to the previous financial year. (For example, an update required by 22 July 2016 relates to FY2015-16 - failure to provide an update will incur the 2015-16 annual charge, and by default will also incur the 2016-17 annual charge (as 16/17 commences on 1 July 2016). Both amounts would be payable by 15 September.	No	No	0.00	-	Not Applicable - TGA Only	0.00	$0.00

Step No.	Description	TGA task	Sponsor task	Sponsor time (hours)	No of Sponsors affected	Class	Sponsor hourly rate	Sponsor total cost
	TGA Financial Services issues a tax invoice to the sponsor for the applicable annual charges.	Yes	No	0.00	-	Not Applicable - TGA Only	0.00	$0.00
	Sponsor pays the annual charge(s) for any non-LVT entries. No further action is required until the next full year annual product charge is incurred.	No	Yes	1.00	335	Clerical and Administrative Workers	53.20	$53.20
	Sponsor notifies that an LVT entry has commenced generating turnover – Sponsors will have the option of notifying the TGA when an entry [subject to an LVT exemption] generates any turnover. Upon receiving the notification, the annual charge exemption will cease and the full year charge will become payable for the year in which turnover was generated.	No	Yes	1.00	335	Clerical and Administrative Workers	53.20	$53.20
	TGA Financial Services issues a tax invoice to the sponsor for the applicable annual charges.	Yes	No	0.00	-	Not Applicable - TGA Only	0.00	$0.00
	Sponsor pays the annual charge(s) for any non-LVT entries. No further action is required until the next full year annual product charge is incurred.	No	Yes	1.00	335	Clerical and Administrative Workers	53.20	$53.20

Step No.	Description	TGA task	Sponsor task	Sponsor time (hours)	No of Sponsors affected	Class	Sponsor hourly rate	Sponsor total cost
	ANNUAL CHARGES INVOICING SCHEDULE **Monthly invoices - $0 turnover entries generating turnover during a financial year** Tax invoices will be issued (monthly) after a sponsors voluntary notification (during the current financial year) that a $0 turnover entry has commenced generating turnover in that financial year. **Example (Monthly Invoices):** A $0 turnover entry commences generating turnover on 1 October. The sponsor notifies the TGA by 22 October that the entry is now generating turnover [**Note.** If the sponsor does not voluntarily notify the TGA of turnover during the year, the sponsor will be invoiced for the year when the sponsor does not make a $0 turnover declaration due by 22 July in the next financial year]. Where a sponsor notification of turnover is received by the TGA during a financial year, an invoice for the applicable full year annual charge will be issued in the next monthly invoice run (i.e. as per the example above, if turnover is recorded for a $0 turnover entry on 1 October, the sponsor may declare the turnover by 22 October for invoicing on 7 November for payment by 7 December) *If a compulsory annual (turnover status) renewal declaration of $0 turnover is not completed by 22 July in the next financial year, it will be assumed the entry was non-LVT in the previous financial year and the applicable annual charge will become payable for that year together with the charge for the current year. They are both payable by 15 September.*							

Step No	Description	TGA task	Sponsor task	Sponsor time (hours)	No of Sponsors affected	Class	Sponsor hourly rate	Sponsor total cost
	Annual invoicing 'Non-exempt entries' Entries which are non-LVT on the next 1 July incur the full year annual charge. Annual invoices are issued in July for payment within 30 days (and again each year thereafter until the entry is cancelled from the Register).							

Option 3 - cease the scheme

(Up to 13 actions [ANNUAL INVOICE + MNTHLY INVOICES] per year)

Step No.	Description	TGA Task	Sponsor task	Sponsor time (hours)	No of Sponsors affected	Class	Sponsor hourly rate	Sponsor total cost
1	**Existing Register entry (at 1 July): If the entry is an existing entry on the Register at 1 July, the full year annual charge is incurred.**	Yes	No	0.00		Not Applicable - TGA Only	0.00	$0.00
2	TGA Financial Services issues the sponsor an existing entry annual charge invoice for the applicable annual charge in July for payment within 30 days.	Yes	No	0.00		Not Applicable - TGA Only	0.00	$0.00
3	The sponsor pays the applicable annual charge. No further action is required until the next full year annual charge is incurred on the (next) 1 July.	No	Yes	1.00	3,679	Clerical and Administrative Workers	53.20	$53.20
4	**New Register entry: If the entry is a new entry in the Register, the full year annual charge is incurred for the year the entry is a new entry.**	Yes	No	0.00		Not Applicable - TGA Only	0.00	$0.00
5	TGA Financial Services issues the sponsor a new entry annual charge invoice for the applicable annual charge. New entry annual product charges invoices are issued to sponsors' on a monthly basis.	Yes	No	0.00		Not Applicable - TGA Only	0.00	$0.00
6	The sponsor pays the applicable annual charge. No further action is required until the next full year annual charge is incurred on the (next) 1 July.	No	Yes	1.00	1,560	Clerical and Administrative Workers	53.20	$53.20

Glossary of terms

Definitions of key terms used in this consultation paper are provided in this section to facilitate a common understanding of the key issues and proposed options.

Australian Register of Therapeutic Goods (the Register): The Register is the publicly accessible reference database of the therapeutic goods available in Australia. The Register is available online https://www.ebs.tga.gov.au. It provides information on therapeutic goods that can be supplied in Australia and includes the product and sponsor name and other basic information about the goods. It is not intended to provide guidance, advice or recommendations on those goods. It is an offence under the Therapeutic Goods Act for a person to import and supply or manufacture and supply therapeutic goods in Australia unless they are entered in the Register in the name of that person (or the goods are otherwise exempt or approved by the TGA).

Therapeutic goods: Therapeutic goods include prescription, over the counter and complementary medicines, medical devices and blood and biological goods that are required to be entered on the Register.

Therapeutic Goods Administration

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Reference/Publication #

Australian Government

Department of Health
Therapeutic Goods Administration

Mr Jason McNamara
Executive Director
Office of Best Practice Regulation
Department of the Prime Minister and Cabinet
1 National Circuit
BARTON ACT 2600

Email: helpdesk@obpr.gov.au

Dear Mr McNamara

Regulation Impact Statement –final assessment second pass

I am writing in relation to the attached Regulation Impact Statement (RIS) prepared for the Low Value Turnover (LVT) Exemption Scheme. The regulatory burden to business, community organisations and/or individuals has been quantified and offsets have been identified and quantified using the Regulatory Burden Measurement framework. These have been agreed with your office.

I am satisfied that the RIS addresses the three key comments raised by your office and notified by Mr Tony Simovski in his letter of 27 February 2015:

- The RIS states the reasons that consultation options 2 and 4 were not considered to be feasible options for achieving the Government's objectives and how these conclusions were made.
- The RIS explicitly discusses the impact of each RIS option on small businesses.
- The RIS provides a description of the proposal's development at each major decision point.

Accordingly, I am satisfied that the RIS now meets best practice consistent with the *Australian Government Guide to Regulation.*

I submit the RIS to the Office of Best Practice Regulation for formal final assessment.

Yours sincerely

Adj Professor John Skerritt
National Manager, Therapeutic Goods Administration
Deputy Secretary, Department of Health
13 March 2015

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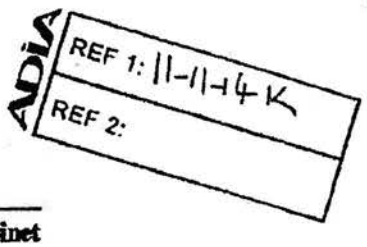
TGA Health Safety Regulation



Australian Government

Department of the Prime Minister and Cabinet
Office of Best Practice Regulation

Reference: 17309
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Adj Prof John Skerritt
National Manager, Therapeutic Goods Administration
Deputy Secretary
Department of Health

Dear Professor Skerritt

Final Regulation Impact Statement – Low Value Turnover (LVT) Exemption Scheme

Thank you for forwarding the Regulation Impact Statement (RIS) for the above proposal, which was received by the Office of Best Practice Regulation (OBPR) for final assessment on 19 March 2015. I note that you have formally certified the RIS as required by the best practice regulation requirements.

The proposal seeks to make amendments to the LVT Exemption Scheme in order to better align the scheme with the Government's Cost Recovery Guidelines, and to reduce the administrative complexity of the scheme. The most significant change to the scheme is that exemptions from paying the annual regulatory charge will only be granted for Register entries which are yet to commence turnover, compared with the current situation which allows exemptions for Register entries with turnovers less than 1.5 times the value of the annual charge.

The changes are estimated to result in a reduction in administrative costs of approximately $3 million per annum, and reduce the cross subsidy between those register entries that qualify for the exemption and those that do not.

The Office of Best Practice Regulation (OBPR) assesses RISs for consistency and adequacy – consistency relates to following the prescribed process and adequacy relates to the quality of the analysis.

I note the agency has been consistent with the RIS guidelines, having twice provided a certified RIS (addressing all seven elements) to the OBPR for final assessment before the decision-maker considers the RIS.

I also note that the RIS is adequate as it does not contain obvious errors and has a degree of detail and depth of analysis that is commensurate with the magnitude of the problem and the size of the potential impact of the proposal. In addition, the regulatory cost estimates have been agreed with the OBPR.

Accordingly, I am satisfied that the RIS meets best practice consistent with the *Australian Government Guide to Regulation.*

For legislation which is tabled in the Parliament, a copy of the RIS must be included in the explanatory memorandum (for primary legislation) or the explanatory statement (for legislative instruments). Please ensure that your officers provide the OBPR with a copy of (or link to) the explanatory memorandum or explanatory statement when these are made public.

Additionally, the OBPR maintains a RIS website and RISs are published as soon as practicable following a regulatory decision being publicly announced. We would appreciate you advising us when a decision on this proposal is announced, and forwarding a final copy of the RIS in *Microsoft Word .doc* format in a form meeting the Australian Government's *Web Content Accessibility Guidelines*. We suggest liaising with your web services team to ensure these guidelines are met. The OBPR should be consulted if the RIS is amended. It is the agency preparing the RIS, not the OBPR, which is responsible for the content of the published RIS.

The website provides a public comment facility on RISs posted on the site. The OBPR moderates this facility for offensive content but does not moderate debate.

Please retain this letter as a record of the OBPR's advice. Our reference number for this issue is 17309. If you have any further queries, please do not hesitate to contact me.

Yours sincerely

Tony Simovski
A/g Deputy Executive Director
26 March 2015